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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/700,434 | 02/28/2001 | Wilfried Fischer | 2727-130 | 5919 |

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| EXAMINER |
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GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/700,434 | FISCHER, WILFRIED |
| | Examiner Sharmila S. Gollamudi | Art Unit 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 May 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,4,5,8,10-15,17-24 and 26-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,4,5,8,10-15,17-24 and 26-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination and Extension of Time received on May 21, 2003 is acknowledged. Claims **1, 4-5, 8, 10-15, 17-24, and 26-32** are pending in this application. Claims 3, 6-7, 9, 16, and 25 stand cancelled.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on Amendment D.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 8, 10-15, 17-24, and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "at least one active ingredient solution or dispersion which is not miscible with water" is unclear. Is the applicant claiming that the drug is hydrophobic or the drug in combination with another solution is hydrophobic? Further clarification is requested. The dependent claims are rejected since they depend off an indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 10-15, 17-22, 24, 26, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Enscore et al WO 98/00118.

Enscore et al disclose a transdermal device including an impermeable backsheet (A), drug matrix with a rate controlling membrane (B), contact adhesive layer (C), and a release liner (D). See (Figure 1). Example 1 discloses the process of making the patch that includes a backsheet of aluminized polyethylene terephthalate, a reservoir gel containing testosterone, hydroxypropylcellulose, and ethanol formed on a EVA copolymer (microporous material) rate controlling membrane, 50 micron pressure-sensitive polyisobutylene adhesive layer, and siliconized polyethylene terephthalate release liner, and. Example 2 teaches a hydroxethylcellulose polymer and a backing membrane made of polyethylene, aluminum, polyester, and EVA. Note the release profile of Figure 3.

Claims 1, 5, 8, 10-12, 17-20, 24, 26-28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/07959.

WO 89/07959 discloses an occlusive body patch for transdermal administration of active agents. WO discloses the method of making a patch that includes a impermeable aluminised polyester backing material (A), nicotine and methylcellulose drug reservoir incorporating a perforated membrane (B), an pressure-sensitive adhesive layer (35 microns thick) (C), an Akrosil 75 micron thick release liner (D). See example 1, abstract, and figures. WO discloses the nicotine is mixed with tee tree oil and then mixed in a water-soluble polymer (example 1).

*It is inherent that the device will release in a surge since both the prior art and the instant device have the same composition. Since the prior art teaches an active and a water-soluble polymer, it is inherent that the polymer will breakdown. The claim does not set forth limitation to distinguish it from the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Enscore et al WO 98/00118.

Enscore et al disclose a transdermal device including a drug matrix, rate controlling membrane, contact adhesive layer, a release liner, and a backsheet. See page 11, lines 17-19. Example 1 discloses a reservoir gel containing testosterone, hydroxypropylcellulose, and ethanol, 50 micron polyisobutylene adhesive layer, EVA copolymer membrane (microporous material), siliconized polyethylene terephthalate

release liner, and a backsheet of aluminized polyethylene terephthalate. Example 2 teaches a hydroxethylcellulose polymer and a backing membrane made of polyethylene, aluminum, polyester, and EVA. The reference teaches the use of materials such as polyurethane, polyethylene, polyester, EVA, etc. for the backing. See page 12, lines 29.

Enscore et al do not exemplify polyurethane.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Enscore and utilize polyurethane as the backing material. One would be motivated since WO teaches the suitability of using polyurethane as backing material.

Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/07959.

WO 89/07959 discloses an occlusive body patch for transdermal administration of active agents. WO discloses the method of making a patch that includes a impermeable aluminised polyester backing material (A), nicotine and methylcellulose drug reservoir incorporating a perforated membrane (B), an pressure-sensitive adhesive layer (35 microns thick) (C), an Akrosil 75 micron thick release liner (D). See example 1, abstract, and figures. WO discloses the nicotine is mixed with tee tree oil and then mixed in a water-soluble polymer (example 1). Further, the reference discloses that nitroglycerine may be substituted for nicotine and teaches the use of testosterone (pg. 11, line 11 and claim 11).

WO does not exemplify nitroglycerine or testosterone.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by WO and utilize nitroglycerine or testosterone. One would be motivated to do so since WO teaches the suitability of other drugs such as nitroglycerine and testosterone in the transdermal patch. Therefore, one would be motivated to choose the drug based on the symptoms to be treated.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable WO 89/07959 or Enscore et al (WO 98/00118) in view of Takayasu et al (5,478,568):

As set forth above, Enscore et al WO 89/07959 teach a transdermal system. Enscore et al exemplify HPC and HEC. WO exemplifies methylcellulose as the water-soluble polymer in the drug layer.

The reference does not specify the use of gelatin as the water-soluble polymer. Takayasu et al teach a transdermal patch. The reference teaches the combination of an active and a water-soluble polymer to increase viscosity and shape-retaining ability of the patch. The polymers taught are cellulose derivative such as HPM, HEC, methylcellulose, gelatin, etc. See column 6, lines 8-25.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute gelatin for the water-soluble polymer. One would be motivated to do so since Takayasu et al teach methylcellulose and gelatin are equivalent in that they are water-soluble polymers that forms gel. Thus, it is obvious to substitute functional equivalent components in the art since one could reasonably expect similar results.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/07959 in view of Place et al (5242391).

As set forth above, WO 95/24172 and WO 89/07959 teach transdermal systems.

The references do not teach the combination of instant drugs.

Place et al teach the treatment of erectile dysfunction. On column 3, a line 12-20, Place discloses the use of testosterone for the treatment of impotence in the prior art. Place teaches the topical application of nitroglycerin to treat impotence (col. 4, lines 30-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a mixture of nitroglycerin and testosterone in a transdermal system. One would be motivated to do so to treat impotence since Place teaches the conventional use of testosterone to treat impotence and teaches the use of nitroglycerine to treat impotence. Thus, a skilled artisan could reasonably expect an additive effect in treating impotence.

Correspondence

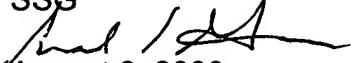
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

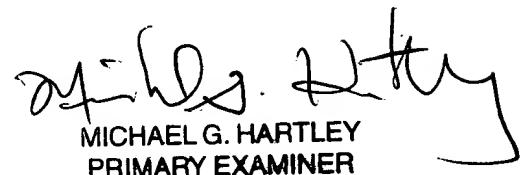
Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



August 8, 2003



MICHAEL G. HARTLEY
PRIMARY EXAMINER